

## **REMARKS**

This Amendment is in response to the Office Action dated August 21, 2006, in which claims 1-40 were rejected. With this Amendment, independent claims 1, 17, and 28-33 are amended. Claims 1-40 are pending in the case, and are presented for reconsideration and allowance. The following remarks are respectfully submitted.

### **I. Rejections under 35 USC §112**

Claims 29-40 stand rejected under 35 USC § 112, first paragraph, as failing to comply with the written description requirement.

With this Amendment, independent claims 29-33 have been amended to address and overcome the rejection. Support in the Specification for the amendments to claims 29-33 can be found at page 6, lines 1-19, page 11, lines 28 and 29, page 13, lines 15-25, and page 8, lines 16-25.

With the amendments to independent claims 29-33, the rejection of claims 29-40 under 35 USC § 112 has been overcome.

### **II. Rejections under 35 USC §103**

#### **A. Claims 1, 2, 4-13, 15-18, 20-34, and 36-38**

Claims 1, 2, 4-13, 15-18, 20-34, and 36-38 stand rejected under 35 USC § 103(a) as being unpatentable over Obel et al. (U.S. Patent No. 5,199,428) and Collins (U.S. Patent No. 5,203,326) in view of Sweeney et al. (U.S. Patent No. 6,400,982).

With this Amendment, each of the independent claims 1, 17, and 28-33 have been amended to define a method or an apparatus which treats a patient to improve cardiac performance and efficiency of the patient's heart through the use of both electrical nerve stimulation to improve balance of a neuro-endocrinological system and the delivery of a pacing therapy to the patient's heart to improve cardiac output. In each of independent claims 28-33, the pacing therapy delivered to improve cardiac output is one of: (a) an overdrive cardiac

patient therapy and (b) a post-extra systolic potentiation therapy. These two therapies are discussed at page 8, lines 16-25 as therapy is provided improved or increased cardiac output.

This unique combination of two different stimulation therapies for improving cardiac performance (e.g., hemodynamics) and efficiency (e.g., balance between supply and demand and balance within the neuro-endocrinological systems) of the patient's heart is not taught or suggested by Obel, Collins, or Sweeney.

Obel is directed to use of vagal stimulation to treat conditions of ischemia. Obel suggests the use of backup brady and tachycardia pacing therapies. (Obel, col. 6, line 66-col. 7, line 2). Obel does not suggest a combined use of electrical nerve stimulation and pacing therapies that increase cardiac output to achieve improved cardiac performance and efficiency.

Collins (U.S. Patent No. 5,203,326) discloses an antiarrhythmia pacemaker that delivers antiarrhythmia therapy using both electrical stimulation of the heart and electrical stimulation of the autonomic nervous system. Collins does not, however, teach the use of nerve stimulation and pacing therapies, which together achieve improved cardiac performance and efficiency. The objective of the particular pacing and nerve stimulation delivered in Collins is to detect and treat arrhythmias in a patient's heart.

Sweeney (U.S. Patent No. 6,400,982) is also directed to arrhythmia prediction and treatment. It briefly mentions the possible use of an additional lead associated with nerves or nerve ganglia at col. 8, line 63 through col. 9, line 2. Sweeney is concerned with predicting and preventing arrhythmias. The therapy delivered by Sweeney and/or including "overdrive pacing" is in the context of and for the purpose of preventing arrhythmias. Sweeney does not teach or suggest combined therapy using both nerve stimulation to provide improved balance of the neuro-endocrinological system and pacing therapies for increasing cardiac output in order to achieve improved cardiac performance and efficiency of a patient's heart.

As amended, independent claims 1, 17, and 28-33, as well as dependent claims 2, 4-13, 15-16, 18, 20-27, 34, and 36-38 are neither taught nor suggested by Obel, Collins, and Sweeney alone or in combination. Rejection under 35 USC § 103 has been overcome and should be withdrawn.

**B. Claims 3, 19, and 39**

Claims 3, 19, and 39 stand rejected under 35 USC § 103(a) as being unpatentable over Obel and Collins in view of Sweeney et al. ('982) in further view of Adams (U.S. Patent No. 5,792,187).

As discussed above, the amendments to independent claims 1, 17, and 28-33 have overcome the rejection based upon the combination of Obel, Collins, and Sweeney. Claim 3 depends from claim 1, claim 19 depends from claim 17, and claim 39 depends from claim 37, which in turn depends from independent claim 33.

Adams (U.S. Patent No. 5,792,187) does not provide the teaching which is missing in Obel, Collins, and Sweeney. Adams teaches the use of neuro stimulation to control pain during the time when a cardioversion/defibrillation shock is being delivered to a patient's heart. Adams is not concerned with a combination of nerve stimulation and pacing therapies which together improve cardiac performance and efficiency of the patient's heart.

As a result of the amendments to independent claims 1, 17, and 33, the rejection of dependent claims 3, 19, and 39 under 35 USC § 103(a) has been overcome. The rejection should be withdrawn.

**C. Claims 14, 35, and 40**

Claims 14, 35, and 40 stand rejected under 35 USC § 103(a) as being unpatentable over Obel and Collins in view of Sweeney et al. ('982) in further view of Sweeney et al. (U.S. Patent No. 6,272,377).

Dependent claim 34 depends from claim 1, and dependent claims 35 and 40 depend from independent claim 33. As a result of the amendments to claims 1 and 33, rejection of claims 14, 35, and 40 has been overcome. As discussed above, Obel, Collins, and Sweeney '982 do not teach or suggest the invention as

defined in independent claims 1 and 33. Sweeney '377 is concerned with arrhythmia treatment, and does not provide the teaching which is missing in the other three references. Claims 14, 35, and 40 are allowable for the same reasons as independent claims 1 and 33 from which they depend.

The rejection of claims 14, 35, and 40 under 35 USC § 103 should be withdrawn.

### **III. Objections to the Specification**

The objections to the Specification under 35 USC § 132(a) relate to the same language that formed the basis for the rejection under 35 USC §112 (discussed above). With the amendments to claims 29-33, the objection under 35 USC § 132(a) has become moot.

With this Amendment, the status of the application on page 1 of the Specification has been updated.

### **V. Conclusion**

Applicants respectfully suggest that all pending claims are in condition for allowance and the Examiner is earnestly solicited to issue a notice of allowance in due course.

Finally, if there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned attorney to attend to these matters. The Commissioner is authorized to charge any deficiencies and credit any overpayments to Deposit Account No. 13-2546.

Respectfully submitted,

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